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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,119	03/11/2004	Yih-Lin Chung	55701-004002	8809

69713 7590 09/09/2008
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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/798,119	CHUNG, YIH-LIN	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-21* is/are pending in the application.

4a) Of the above claim(s) *2-4, 6-10, 12, 13, and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 1-4 and 6-21 are pending. However, only claims 1, 11, and 14-17 are the subject of this Office Action, as claims 2-4, 6-10, 12, 13, and 18-21 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142(b). Applicants, in their action of 11 June 2008 cancelled claim 5.

Applicant's arguments and amendments filed on 11 June 2008 in response to the Non-Final Rejection filed by this Office on 08 April 2008 have been fully considered, but they are not deemed to be persuasive. Rejections and objections not reiterated from previous office actions are hereby withdrawn. The below constitutes all rejections pending.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11, and 14-16 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,877,213 [hereinafter referred to as "Samid"].[1]

This Office's arguments from its actions of 23 March 2007, 01 October 2007, and 08 April 2008 are incorporated herein by reference in their entirety.

[1] Cited on PTO Form 892 filed on 23 March 2007.

The Applicant's argument that Samid does not establish a *prima facie* case of obviousness, because the present invention is distinguishable due to its focus on promoting cell proliferation and survival rather than promoting cell death has been considered, but it is not deemed persuasive for the reasons of record set forth in this Office's previous actions mentioned *supra*. Additionally, Applicant now argues that Samid is an inapplicable reference, because of the patient population the hyperacetylating agent is to treat. Applicants argue that Samid treats patients with anemia, cancer, AIDs or severe β-chain hemoglobinopathies rather than those patients suffering from chemotherapy or radiotherapy induced side effects and therefore, is not applicable as prior art in the instant case.

As noted previously, claims are to be given their broadest reasonable interpretation and the claims as written in this application, apply for increasing therapeutic gain associated with tumorigenesis where a patient undergoes radiotherapy or chemotherapy tumorigenesis has a direct correlation to malignancy and/or nonmalignant of dense structures.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to administer sodium phenylbutyrate in the manner prescribed by Samid, in combination with radiotherapy, as a method of treating tumorigenesis.

Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,877,213 [hereinafter referred to as "Samid"] in view of Shufeng, Z., et al., *5,6-Dimethylxanthenone-4-acetic acid (DMXAA): A New Biological Response Modifier for Cancer*

Therapy, Investigational New Drugs, vol. 20, 2002, pages 281-295 [hereinafter referred to as "Shufeng, et al."].[2]

The teachings of Samid, taught in this Office's actions of 23 March 2007 and 01 October 2007 are incorporated herein by reference as are the teachings of Shufeng et al from this Office's action of 01 October 2007 as well as the arguments, supra, regarding the applicability of the Samid reference to the instant set of claims.

One of ordinary skill in the art would be motivated to combine the teachings of Samid with the teachings of Shufeng et al., because the references teach overlapping subject matter, most notably, the administration of anti-tumor agents.

In light of the foregoing, one of ordinary skill in the art would be motivated to apply the teachings of Samid and the teachings of Shufeng et al to the present invention, because DMXAA is an anti-cancer agent/biological response modifier that when combined with radiotherapy and/or phenylacetic acid and its pharmaceutically acceptable salts and derivatives, including sodium phenylbutyrate, effectively treats various cancers. When used together, in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors would be treatable through the combination therapy of sodium phenylbutyrate and DMXAA with radiotherapy.

Conclusion

No claims are allowed.

[2] Cited on PTO Form 892 filed on 23 March 2007.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614